

July 22, 2005

Reference: Docket No. 2005D-0169

Gold Standard, Inc.
320 W. Kennedy Blvd. Suite 400
Tampa FL, 33606

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

Gold Standard, a commercial vendor in the Drug Informatics market, respectfully submits the following comments in regard to the Food and Drug Administration's (FDA) *Draft Guidance on Useful Written Consumer Medication Information* (Federal Register: May 26, 2005, Volume 70, Number 101; Page 30467-30469).

Gold Standard is grateful to the FDA for the *Draft Guidance*. It is certainly helpful to have the agency's view of what will qualify as "useful" Consumer Medication Information (CMI) to achieve the goals stated in the 1996 *Action Plan for the Provision of Useful Consumer Medicine Information (Action Plan)* and the legislation of U.S. P.L. 104-180. It is Gold Standard's desire to work with the FDA and in collaboration to successfully achieve the goals desired.

By way of introduction, Gold Standard established in 1993, and has largely been known for its electronic referential drug information offerings. With time, the company has focused on providing drug information and other clinical services and solutions through enhanced technologies. Today, we provide electronic-based referential services to over 20,000 retail pharmacies, and are the source of drug information for many health care systems, physicians, and managed care operations. Our content includes professional level clinical information and consumer information in English and Spanish. This year, we will be also offer an integrated drug informatics database for end user systems. Gold Standard anticipates that our unique decision support offerings will be used widely in the pharmacies of our current and future clients; use which will include the provision of CMI.

Review and Commentary:

In review of the *Draft Guidance*, Gold Standard finds need to communicate concerns generated from the proposed guidance. The concerns may be relegated to 2 main topics: 1) Concerns regarding the progress and implementation in the private sector within current established timelines; and 2) Concerns regarding successful achievement of public health comprehension and literacy goals given the expanse of details contained in the *Draft Guidance*.

A. Concerns regarding the progress and implementation in the private sector within current established timelines:

Like many vendors, Gold Standard has actively taken the information from the Svarstad study and the subsequent publication of the Action Plan as our cornerstone from which to build our CMI compliance. These steps have been under active construct since 2000. It is unfortunate that the *Draft Guidance* following the Action Plan has been provided so late in the legislative timeframes.

As the FDA is aware, there is often limited capability of developers to change database structures and related content in response to new or changed implementation guidelines, if such guidelines change late in the development process. Likewise, the end users of any electronic based CMI data system have limited capacity to respond quickly to changes in data content, organization, the suggested portals of CMI delivery, or changes that directly impact printing and provision in dispensing workflow. Major changes needed by either side would clearly take beyond the 2006 deadline to successfully implement and be deemed satisfactory by the FDA. Time is of the essence if vendors, especially newcomers to the arena, are to successfully meet the 2006 deadline. Clearly, success cannot be expected if the final rules of guidance continue to be delayed or changed throughout the legislatively mandated period.

Gold Standard respectfully submits the following suggestions regarding timelines to the FDA, with the emphasis on collaboration between the FDA and key groups:

- 1) Suggest the FDA quickly, in collaboration stakeholder groups (e.g., content vendors, pharmacies, health care experts, literacy experts, consumers), finalize a *Guidance* that will represent “best practices” to develop and implement successful, objective CMI from the agency’s perspective in accordance with the Action Plan and public legislation.
- 2) Provide for publishers and other stakeholders the specific research design that FDA will use to conduct the final assessment of CMI in 2007 following the 2006 timeframe.
- 3) Establish the results of the 2007 CMI assessment as a mid-course evaluation, rather than final assessment. A final assessment of private sector CMI could be conducted in 2010 rather than 2007, which would align timelines in congruence with the FDA-led goals relating to Healthy People 2010 (e.g., Medical Product Safety Objective 17-4).

B. Concerns regarding successful achievement of public health comprehension and literacy goals given the expanse of details contained in the *Draft Guidance*:

Gold Standard has agreed with the Action Plan criteria for defining useful CMI and has been committed to conforming our CMI content and format to the Action Plan.

However, Gold Standard has specific concerns regarding the FDA's current interpretation of the Action plan as provided in the *Draft Guidance*. In particular, the guidance on particular descriptive elements gives the impression that essentially the same information that is listed in the Package Insert will be required to be reproduced in consumer friendly form. The concern is that the resulting CMI document, particularly for selected high-profile medications, will become quite lengthy or may highlight clinical points that, out of context of health care professional interpretation, could be a deterrent to medication safety and adherence.

Gold Standard agrees that the Package Insert should provide the basic foundation of information for the CMI document; however, the limitation that the Package Insert be the only accepted reference for compliance of information contained in CMI regarding precautions, interactions or side effects may be limiting in terms of scientific accuracy. Additionally, the length of content or depth of content resulting from adherence to some of the guidance recommendations could be counterproductive to health care literacy, comprehension, and medication compliance. The complexities of the descriptive information required could also make it difficult to adhere to desired formats that include plenty of white-space, bullets, and contrast for readability.

Gold Standard respectfully submits the following suggestions regarding content of CMI to the FDA with the emphasis on collaboration between the FDA and key groups:

- 1) Provide publishers with specific examples of compliant CMI for a selected subset of commonly prescribed drugs and additionally provide feedback to publishers regarding their compliance with the CMI Guidance through prototype review.
- 2) Provide opportunity for publishers to discuss the *Draft Guidance* with the FDA in the context of specific clinical concerns and practical patient examples of those concerns.

Conclusion:

Clearly, while Gold Standard shares a business interest in the continued provision of CMI through private vendors, this interest is set aside for the purposes of this commentary. The improper use of medications, or lack of use to achieve maximum benefit, costs our health care system and individual patients dearly every year, not only financially, but clearly in terms of morbidity and mortality. Gold Standard and our subsidiary, Informed Decisions, LLC, are committed to drug information content and technology solutions that improve public health and contribute to the appropriate prescription and use of medications by health care professionals and consumers in the United States.

Gold Standard is thankful to have had this opportunity to comment to the FDA.

Respectfully submitted,

A handwritten signature in cursive script that reads "Mary Ann Natchez, PharmD BCPS".

MaryAnne Hochadel, PharmD BCPS
Vice President and Editor-in-Chief
Gold Standard, Inc.

References:

1. Public Law 104-180, Title VI, Sec 601 Effective Medication Guides, 110 Stat 1593 (1996).
2. Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, available on the Internet at <http://www.fda.gov/cder/offices/ods/keystone.pdf>.
3. Svarstad, B.L. and J.K. Mount, Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001, final report to the U.S. Department of Health and Human Services and the Food and Drug Administration, December 2001, available on the Internet at <http://www.fda.gov/cder/reports/prescriptioninfo/default.htm>.